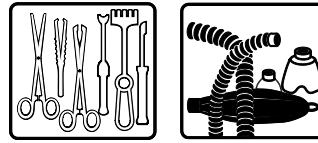




neodisher® SeptoClean



Cleaning and disinfecting agent with activity against prions for reprocessing thermostable and thermolabile instruments

Liquid concentrate

Fields of application:

- Automated reprocessing of thermostable and thermolabile instruments in washer disinfectors
- Also suitable for the automated and manual disinfecting pre-cleaning with activity against prions

Performance Spectrum:

- Reliably removes blood, protein and other residues commonly appearing during operations
- Suitable for surgical instruments made of stainless steel, titanium, chromium-plated or nickel-plated brass and hard metal as well as for anaesthetic utensils
- With titanium and titanium alloys, colour changes might occur due to a change in the thickness of the colour-producing titanium oxide layer

Special properties:

- All-purpose detergent based on alkalis and surfactants
- Prion destabilising, inactivating and decontaminating activity. Confirmed by certification¹
- For a preventive minimisation of the infection risk of prion-related diseases (TSE²), that is with all patients without an express suspicion of CJD /vCJD
- Bactericidal, yeasticidal, and virucidal activity. Confirmed by certification according to EN standards³ and RKI/DVV⁴
- Excellent material compatibility

Application and dosage:

neodisher SeptoClean can be used in washer disinfectors. Depending on the desired activity it can be used in various types of automated reprocessing processes. Typical program cycles for achieving the desired activities are mentioned below:

¹ Tested according to the method of J. Bertram, M. Mielke, M. Beekes, K. Lemmer, M. Baier, G. Pauli: Inaktivierung und Entfernung von Prionen bei der Aufbereitung von Medizinprodukten, Ein Beitrag zur Prüfung und Deklaration geeigneter Verfahren, Bundesgesundheitsblatt - Gesundheitsforschung - Gesundheitsschutz 2004 · 47: 36 - 40

² TSE = transmissible spongiform encephalopathies

³ European Standards EN 13727, EN 14561, EN 13624, EN 14562, EN 14476

⁴ according to the guidelines of the Robert-Koch-Institute (RKI) and the Deutschen Vereinigung zur Bekämpfung von Viruskrankheiten (DVV) [German Association for the Control of Virus Diseases]

• Automated cleaning and thermal disinfection:

Process step	Parameters
Pre-cleaning	Cold water
Cleaning*	1 - 3 ml/l (0.1-0.3 %)
Neutralisation (optional)	1 ml/l (0.1 %) neodisher Z
Intermediate rinse	
Final rinse with thermal disinfection	Deionised water, 5 min., 90 °C

* The working concentration depends on the degree of decontamination of the medical devices to be reprocessed.

• Automated cleaning with prion destabilising activity and thermal disinfection:

Process step	Parameters
Pre-cleaning	Cold water
Cleaning	5 ml/l (0.5 %), 5 min., 55 °C
Neutralisation (optional)	1 ml/l (0.1 %) neodisher Z
Intermediate rinse	
Final rinse with thermal disinfection	Deionised water, 5 min., 90 °C

• Automated cleaning with prion destabilising, inactivating and decontaminating activity and thermal disinfection

Process step	Parameters
Pre-cleaning	Cold water
Cleaning	10 ml/l (1.0 %), 10 min., 55 °C
Neutralisation (optional)	1 ml/l (0.1 %) neodisher Z
Intermediate rinse	
Final rinse with thermal disinfection	Deionised water, 5 min., 90 °C

• Automated cleaning with prion destabilising, inactivating and decontaminating activity and chemical disinfection** (SeptoClean process)

Process step	Parameters
Pre-cleaning	Cold water
1. Cleaning step	5 ml/l (0.5 %), 5 min., 55 °C
2. Cleaning step incl. chemical disinfection** (bactericidal, yeasticidal, virucidal)	10 ml/l (1.0 %), 10 min., 55 °C
Neutralisation (optional)	1 ml/l (0.1 %) neodisher Z
Intermediate rinse	
Final rinse	Deionised water, 55 °C - 70 °C

** Not suitable for high level disinfection of semi-critical medical devices

• Automated disinfecting pre-treatment (e.g. in the surgery area) with activity against prions prior to central reprocessing:

Activity	Parameters
Pre-cleaning with prion inactivating and decontaminating activity as well as chemical disinfection (bactericidal, yeasticidal and active against enveloped viruses [incl. HIV, HBV, HCV])	10 ml/l (1.0 %), 10 min., 55 °C
Neutralisation (optional)	1 ml/l (0.1 %) neodisher Z
Final rinse	Deionised water



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In the cleaning step softened water resp. water with max. 0.9 mmol/l should be used. We recommend deionised water for rinsing to achieve optimum results. When reprocessing ophthalmic instruments the use of a neutralising agent is generally recommended. In each of the above-mentioned processes, neodisher MediKlar special (0.2 – 0.4 ml/l) can be added to the rinse water for shortening the drying time

- For the pre-treatment of instruments neodisher SeptoClean can be used in dip and ultrasonic baths prior to central reprocessing. Depending on the desired activity the application parameters are as follows:

Activity	Parameters
Pre-cleaning with chemical disinfection (bactericidal, yeasticidal and active against enveloped viruses) or Pre-cleaning with prion-destabilising, prion-inactivating and prion-decontaminating activity	20 ml/l (2.0 %), 30 min., 20 °C 10 ml/l (1.0 %), 60 min., 23 °C
Neutralisation (optional)	1 ml/l (0,1 %) neodisher Z
Rinsing	Deionised water

Automated reprocessing must be carried out immediately after treatment in a dip or ultrasonic bath. In case of longer waiting times, rinse off possible residues of the neodisher SeptoClean working solution with water in order to avoid the drying of the working solution residues on the instruments.

Should the neodisher SeptoClean working solution dry on the instruments white stains are formed which are difficult to remove. Rinse fresh splashes and drops with water or remove them with a cloth. Drying stains in dip and ultrasonic baths have no influence on the efficacy of the process or the functionality of the baths.

General instructions on use:

- For professional use only.
- Use suitable dosing devices for dosing.
- The neodisher SeptoClean working solution has to be rinsed off completely (preferably with deionised water).
- Rinse out dosing system and suction hose with water before changing product.
- Reprocessing should comply with all ordinances pursuant to the Medical Device Directive and should be performed with appropriate validated processes.
- Please observe the instrument manufacturer's recommendations for use according to the requirements of DIN EN ISO 17664.
- The instructions given by the manufacturer of the washer disinfectant are to be observed.
- Do not mix with other products.

Expert reports:

The disinfecting activity and the activity against prions have been confirmed by certification. Expert reports are available on request.

Technical data:

pH-range	11.3 - 12.3 (1 - 10 ml/l, determined in deionised water, 20 °C), 10.2 - 11.2 (1 - 3 ml/l, determined in deionised water, 20 °C)
Density	1.4 g/cm ³ (20 °C)
Viscosity	< 50 mPa s (concentrate, 20 °C)
Titration factor	0.71 (according to neodisher titration instructions)

Ingredients:

Ingredients according to Regulation (EC) No 648/2004 on detergents:
< 5 % non-ionic, cationic and amphoteric surfactants
15 - 30 % phosphates

CE-mark: 0297

neodisher SeptoClean conforms to the European directive 93/42/EC, Annex I concerning medical devices.

Storage information:

Always store at a temperature between -15 °C and 30 °C. Usable for 2 years when stored as recommended. For expiry date refer to the stamp mark on the label behind the hourglass symbol

Hazard and precautionary statements:

For safety information see EC safety data sheets. These are available at www.drweigert.com under the category "Service/Downloads".

Dispose only when container is empty and closed. For disposal of product residues, refer to the Safety Data Sheet.

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With the above information, to our current knowledge we describe our product regarding safety necessities, but we do not involve any quality description or promise certain properties.